FEB 24 2014

ThermoFisher
SCIENTIFIC

510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Premarket Notification 510(k) No: k133404

Date of Summary Preparation: January 8, 2014

Distributor:
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002
269-492-1957

Manufacturer:
Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala, Sweden

Company Contact Person:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4165 Commercial Avenue
Portage, MI 49002
269-492-1957

Device Names:
ImmunoCAP Total IgE System, consisting of
- ImmunoCAP Total IgE Conjugate
- ImmunoCAP Total IgE Anti-IgE
- ImmunoCAP Total IgE Calibrators
- ImmunoCAP Total IgE Curve Controls
- ImmunoCAP Total IgE Control LMH

Common Name:
Automated in vitro quantitative assay for the measurement of Total IgE.

Classification:

Product Code	DGC
Class	II
CFR	866.5510

Substantial Equivalence to:

ImmunoCAP Total IgE	k964152

Indications For Use Statements

ImmunoCAP Total IgE system

ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories. ImmunoCAP Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.

ImmunoCAP Total IgE Control LMH

ImmunoCAP Total IgE Control LMH is used for monitoring ImmunoCAP Total IgE measurements performance in Phadia instruments.

Device Description

Reagents

ImmunoCAP Total IgE reagents and control are modular in concept and are available individually. For a complete listing of reagents needed to perform the ImmunoCAP Total IgE assay, please consult the ImmunoCAP Total IgE Directions for Use.

Instrument System

Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000 instruments with associated software process all steps of the assay and calculate results automatically after the assay is completed.

ImmunoCAP Total IgE, Test Principle

Anti-IgE, covalently coupled to ImmunoCAP, reacts with the total IgE in the patient sample. After washing, enzyme labeled antibodies against IgE are added to form a complex. Following incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The fluorescence is directly proportional to the concentration of IgE in the sample. The higher the response, the more IgE is present in the sample. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

Description of change

Three current Directions for Use have been merged to one assay specific Directions for Use. This is only a change to the format of the Directions for Use for ImmunoCAP Total IgE System, including minor editorial changes.

Conclusion

The change does not affect the Intended Use / Indications for Use Statement and it does not affect the safety or effectiveness of the ImmunoCAP Total IgE system, as cleared under k964152.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2014

PHADIA US INC.
C/O MR. MARTIN R. MANN
SENIOR REGULATORY AFFAIRS MANAGER
4169 COMMERCIAL AVENUE
PORTAGE, MI 49002

Re: k133404
Trade/Device Name: ImmunoCAP Total IgE
ImmunoCAP Total IgE Control LMH
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: II
Product Code: DGC, JJX
Dated: February 4, 2014
Received: February 5, 2014

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k133404

Device Name
ImmunoCAP Total IgE System

Indications for Use *(Describe)*
ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories. ImmunoCAP Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth FDA Stafford -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k133404

Device Name
ImmunoCAP Total IgE Control LMH

Indications for Use *(Describe)*
ImmunoCAP Total IgE Control LMH is used for monitoring ImmunoCAP Total IgE measurements performance in Phadia instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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